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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,705	08/02/2001	Richard M. Amasino	960296.97214	6991

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David M. Kettner
Quarles & Brady LLP
1 South Pinckney Street
P.O. Box 2113
Madison, WI 53701-2113

EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/920,705	Applicant(s) AMASINO ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 11/18/2005 has been entered.

Claims 1-27 are pending.

Claim 27 has been withdrawn from consideration for being drawn to a non-elected invention.

2. Claims 1-26 including SEQ ID NO:2 in sense orientation will be examined in the present office action.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

5. This application contains claim 27 drawn to an invention nonelected with traverse filed 5/29/2003 and 6/29/2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

6. The specification remains objected to for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences. See for example page 19, paragraph 74, and page 21, paragraph 77. This objection is maintained for the reasons of record set forth in the Official

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action mailed 5/18/2005. Applicant's arguments filed 11/18/2005 have been fully considered but they are not persuasive.

Applicants contend that the primer sequences are incorporated into SEQ ID NO:4 or 5 (page 2 and 3 of amended specification filed 11/18/2005).

The Office contends that each sequence is required to have its own sequence identifier, even if it is incorporated into another sequence.

Claim Objection

7. Claims 1, 8, and 16 are objected to for being drawn to a non-elected invention, i.e., "antisense".

Claim 13 is objected to for not reciting the verb "is" between "sequence" and SEQ ID NO:2.

Claim 24 is objected to for misspelling "thaliana".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10-11 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-11 and 17-18 recite the limitation "wherein the transgenic plant" in claim 8 or 16. There is insufficient antecedent basis for this limitation in the claim.

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Claim 23 recites the limitation "the sequence" in claim 22. There is insufficient antecedent basis for this limitation in the claim. It is unclear to which "sequence" Applicant is referring.

Claim 25 recites the limitation "DNA sequence" in claim 24. There is insufficient antecedent basis for this limitation in the claim. It is unclear to which "DNA sequence" Applicant is referring.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 6-12, 14-19, 21-22, 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite "the FPA polynucleotide having a coding region which has at least 50% (or 80%) sequence identity to SEQ ID NO:2" or "the protein having at least 80% sequence identity to SEQ ID NO:3". Applicants fail to point to support for the phrase in the instant specification. Upon a cursory search of the specification, support could not be

found. Applicants are required to point to support for the above recited phrases or to amend the claims to delete the NEW MATTER.

Written Description

10. Claims 1-4, 6-12, 14-19, 21-22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/18/2005. Applicant's arguments filed 11/18/2005 have been fully considered but they are not persuasive.

Applicants contend that they have demonstrated that there are other FPA genes in plants and this entitles the Applicants to the claimed breadth (page 9 of Remarks, top paragraph). Applicants contend that the claimed 50% sequence identity along with the claimed function meet the requirements for patentability under 35 U.S.C. 112, first paragraph.

The Office contends that Applicants have not pointed to locations in the specification where other FPA genes are disclosed. The Office contends that Applicants have only disclosed one genomic sequence for the FPA gene from Arabidopsis, and said sequence is set forth in SEQ ID NO:1. The cDNA sequence for the FPA gene is set forth in SEQ ID NO:2 and its deduced amino acid sequence is set forth in SEQ ID NO:3 (page 7, paragraph 27). Applicants have not disclosed any polynucleotide sequences which have at least 50% sequence identity to SEQ ID NO:2 and encode a protein with the same activity and function as the protein encoded by SEQ ID NO:2. Applicants fail to describe a representative number of polynucleotide sequences from

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a representative number of plants encoding a FPA protein falling within the scope of the claimed genus of polynucleotides. Applicants do not identify essential regions of the FPA polynucleotide of SEQ ID NO:2 or FPA protein encoded by SEQ ID NO:2, nor do Applicants describe a genus of FPA polynucleotide sequences that encode a FPA protein with the same function as the FPA protein encoded by SEQ ID NO:2.

Scope of Enablement

11. Claims 1-22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 and 2 encoding SEQ ID NO:3, a transgenic plant comprising a transgene comprising SEQ ID NO:2 in sense orientation, a plant or plant seed comprising a genetic construct comprising SEQ ID NO:2 in sense orientation, wherein the transgenic plant, plant or plant seed will flower early compared to a plant not comprising said transgene, or construct; or a method for increasing the time to flowering in Arabidopsis comprising transforming Arabidopsis with a construct comprising SEQ ID NO:1 or 2 operably linked to a promoter in sense orientation, wherein SEQ ID NO:1 or 2 encode the polypeptide of SEQ ID NO:3, does not reasonably provide enablement for SEQ ID NO:1 or 2 encoding SEQ ID NO:3 and plant transformation therewith, to produce a plant that has an altered flowering time, wherein the altered flowering time is a delayed flowering time; or any isolated DNA sequence comprising the coding sequence for any FPA gene which has at least 50% sequence identity to SEQ ID NO:2 and plant transformation therewith, or method of producing a transgenic plant with altered flowering characteristics comprising introducing said DNA sequence into a plant. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a transgenic plant, plant, or plant seed comprising in its genome a transgene or genetic construct comprising the coding sequence for any FPA gene which has at least 50% sequence identity to SEQ ID NO:2 in sense orientation which causes the plant to have an altered flowering time as compared to non-transgenic plants of the same species, or wherein the FPA polynucleotide is from Arabidopsis, or wherein the FPA polynucleotide has the sequence set forth in SEQ ID NO:2, or seed from said transgenic plant or plant from said seed; an isolated DNA sequence comprising the coding sequence for the FPA gene from Arabidopsis, the FPA polynucleotide having a coding region which has at least 80% sequence identity to SEQ ID NO:2, or an isolated DNA sequence comprising a DNA sequence encoding the FPA protein from Arabidopsis, the protein having at least 80% sequence identity to SEQ ID NO:3; or method of producing a transgenic plant with altered flowering comprising a genetic construct comprising

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a plant expressible promoter and an FPA polynucleotide having a coding region which has at least 50% sequence identity to SEQ ID NO:2.

Applicants isolated the FPA gene by positional cloning performed on *fpa* mutants of the Columbia ecotype of Arabidopsis. Applicants were able to complement the *fpa* mutants using clones comprising genomic DNA from BAC 1024. The rescued clones all contained the same region of DNA (page 18, paragraphs 68-71). Applicants disclose the sequence for the entire FPA gene from Arabidopsis is set forth in SEQ ID NO:1. The cDNA protein coding sequence for the FPA gene is set forth in SEQ ID NO:2 and its deduced amino acid sequence is set forth in SEQ ID NO:3 (page 7, paragraph 27). Applicants disclose Arabidopsis plants transformed with a construct comprising the entire FPA gene from Arabidopsis exhibited early flowering compared to Arabidopsis plants not transformed with said construct (pages 19-20, paragraphs 74 and 75).

The state-of-the-art teaches transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the

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respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

Applicants claims are broadly drawn to plants in which the flowering time has been *altered*. The recitation “altered” encompasses plants that flower early and those that flower later than wild-type. Applicants have disclosed that transforming plants with SEQ ID NO:2 produced plants that exhibit early flowering, as discussed above. Therefore, it is unclear how transforming a plant with SEQ ID NO:2 will also produce a plant that has delayed flowering. Therefore, claims drawn to plants with altered or delayed flowering are not enabled.

Re: claim 8 is drawn to a plant comprising a genetic construct comprising Applicants’ polynucleotide. The Office interprets this to mean in part, that a plant acquired the genetic construct through traditional breeding practices. Therefore, it is unclear why Applicant is comparing said plant to a non-transgenic plant (claim 8, line 4). See also claim 16, line 6.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:2 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce plants that exhibit an early flowering phenotype.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

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Applicant's arguments filed 11/18/2005 have been fully considered but they are not persuasive.

Applicants contend that they have demonstrated that multiple FPA genes exist and have provided structural limitations which provide breadth to the invention. Applicants contend they have given "clear notice to those with skill in the art what is within or without the scope of the present invention (page 9 or Remarks, 1st full paragraph).

The Office contends that Applicants have not pointed to locations in the specification where other FPA genes are disclosed. Applicants have not disclosed how one skilled in the art would identify and isolate polynucleotide sequences encoding proteins having the same activity/function as the protein encoded by SEQ ID NO:2 from the multitude of sequences that are encompassed by Applicants broad claims. Other than SEQ ID NO:2, Applicants have not transformed a plant with any polynucleotide having less than 100% sequence identity to SEQ ID NO:2. As stated above, undue trial and error experimentation would be required for one of ordinary skill in the art to practice the claimed invention.

12. Claims 1-26 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:2 encoding SEQ ID NO:3, and transgenic plant, plant, plant seed or method comprising said polynucleotide.

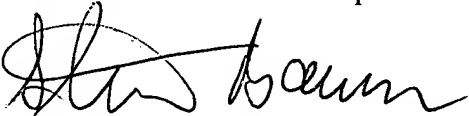
13. No claims are allowed.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" and last name "Baum" clearly distinguishable.

Stuart F. Baum Ph.D.

Patent Examiner

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January 31, 2006